Remarks/Arguments

Claims 3, 4, 12, and 13 were previously withdrawn from consideration in response to a restriction requirement. Claims 1, 2, 5-11 and 14-18 are presently under consideration and have been rejected. Applicants are submitting claim amendments with this response. Please cancel claims 1, 2, 5-11 and 14-18. Please enter new claims 19-24. A listing of the claims accompanies this response and begins on page 2 of this paper.

Claims 5, 6, 8, 14, 15 and 17 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite due to the use of the phrase "analog of lysophosphatidic acid" in those claims. The amended claims do not contain the phrase "analog of lysophosphatidic acid."

Claims 1, 2, 5, 6, 8-11, 15, 17, and 18 were rejected under 35 U.S.C. 112, first paragraph, because the specification, which the examiner has indicated to be enabling for a therapeutic method comprising administering PPARγ antagonists such as those recited in claim 7, does not "reasonably provide enablement for a method comprising administering any compound that inhibits signaling through PPARγ." Applicants respectfully traverse the examiner's rejection. Both the originally-presented claims and the presently-presented claims are directed to a method for inhibiting neointima formation. It is not necessary to search far and wide for compounds that will accomplish this purpose. As the examiner indicated, claim 7 recites such compounds (as does the specification). The specification also teaches a method for readily identifying compounds that inhibit LPA-induced PPARγ activation.

The examiner cited In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) for factors that are determinative in deciding whether practice of a disclosed invention would require undue experimentation. Applicants respectfully disagree with the assertion that the claimed invention "encompass[es] methods comprising administering any chemical substance whatsoever." Clearly, a multitude of compounds exist which do not function to inhibit LPA-induced PPARγ activation. Should one of skill in the art wish to utilize the method, the specification describes compounds that do inhibit LPA-induced PPARγ activation, and provides a method for screening other compounds that will inhibit neointima formation via their inhibition of LPA-induced PPARγ activation. The examiner has already stated that the specification is "enabling for a therapeutic method comprising administering certain specific PPAR-γ antagonists such as those recited in claim 7."

The examiner's reasoning that applicants are required to provide "an exhaustive list" of all possible PPARγ antagonists, that working examples of actual methods of treating disease in humans must be presented, and that it would be necessary to "gather[] this data for every compound known to man," including the performance of human tests . . . "to establish the activity or lack thereof of every possible adenosine A_{2A} *(?)* antagonist" puts a burden on a prospective patentee that is undue—and not in keeping with the statute and the case law.

Animal models of disease exist to allow studies to be performed to determine the effectiveness of therapies for their intended purpose without requiring the considerable expense and organizational effort that accompanies human studies. Such animal models are accepted within the scientific community. The inventors present data

obtained from accepted animal models of neointima formation and associated development of atherosclerosis. While additional studies, including human clinical trials, would be necessary in order to obtain regulatory approval for a compound for human use in the method of the invention, those requirements are placed on the applicants by a separate agency of the United States Government—the Food and Drug Administration. The United States Patent and Trademark Office has long held the position that it is not the duty of the Patent Office to make such determinations.

According to MPEP §2164.06:

> The quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *In re Wands*, 858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Time and expense are merely factors in this consideration and are not the controlling factors. *United States v. Telectronics Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cert. denied, 290 U.S. 1046 (1989).

It is not necessary to screen 26 million compounds in order to practice the method of the present invention. Rather, it is only necessary to utilize one of the described compounds, or to identify other compounds based upon their properties as inhibitors of LPA-induced PPARγ activation. Methods for screening compounds for that purpose are described in the specification. Furthermore, given the disclosure provided

by the inventors and the list of compounds that will achieve the purpose of inhibiting LPA-induced PPARγ activation, it is well within the skill of one in the field of medicinal chemistry or pharmaceutical science to synthesize or identify additional compounds that may accomplish this same purpose. As stated in *Wands*, it is sufficient if the "specification in question provides *a reasonable amount of guidance with respect to the direction in which the experimentation should proceed*." (In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), emphasis added.)

The examiner is correct in stating that patent is not a hunting license. However, the Genentech case cited by the examiner also states that a patent is a reward for the "successful conclusion" of a search. (Genentech, Inc. v. Novo Nordisk A/S, 108 F. 3d 1361 at 1366 (Fed. Cir. 1997).) The court also stated in that case that "[e]very aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification," but "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." Applicants submit that reasonable detail has been provided. There is no requirement that applicants describe each and every compound by which a method may be achieved. Applicants have placed within the hands of those of skill in the art a list of compounds that may be used in the method of the invention, and have described a method by which individuals skilled in the art of medicinal chemistry and/or pharmaceutical sciences may identify other compounds that achieve a similar effect. Given an appropriate method for screening compounds, especially in light of the fact that a list of effective compounds has been described, identification of other compounds for use in the method of the invention may require experimentation, but that experimentation would not, according to

the standards set forth in cases such as Wands and Genentech, rise to the level of undue experimentation.

Applicants believe that they have described a method that will be of benefit for therapeutic use, that they have described compounds effective for use in the method, and that their disclosure of these compounds and methods for screening compounds for use in the method enables individuals skilled in the chemical and biotechnological arts to identify other compounds for use in the method. Applicants also believe that the claims are in condition for allowance, and a notice of allowance is respectfully requested.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria VA 22313-1450 on October 13, 2007.

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